

### **DETAILED ACTION**

Receipt is acknowledged of the amendment filed 02/22/2008.

The rejection of claims 21-25, 27-30 over Arras et al in combination with Robinson et al is maintained in this action. The substance of the rejection is found in the prior office action.

### ***Response to Arguments***

Applicant's arguments filed 02/27/2008 have been fully considered but they are not persuasive.

Applicant argues that the newly amended claims referring to "at least one pellet having at least two therapeutic agents one of which contains cells" is neither taught nor suggested by the references. However, as stated in the rejection, Arras teaches the microencapsulation of growth factors. This broadly encompasses the "at least one pellet" of the claims. Further, the combination of the growth factors of Arras et al, with the cells provided by Robinson et al would read on the "at least two therapeutic agents". It is therefore it is not agreed that the combination of the references does not read on the currently amended claims.

As stated above, the current claims read on a pellet generically, which includes microparticles as taught by Arras et al. It is therefore suggested that applicant amend

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the claims to include the size limitations for these pellets as set out at page 14, lines 29-31. Pellets of this magnitude are neither disclosed, nor suggested by the combined references.

The following are new rejections of the claims based on the latest amendment of 02/27/2008.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 21-30 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The limitation referring to "at least one pellet" is not supported by the original specification and is considered new matter. Correction is requested.

The limitation referring to the second therapeutic agent therapeutic agent which "contains implantable cells" is unclear in that it is not understood how a therapeutic agent can serve as a carrier for such cells. Clarification is requested since a carrier is

not considered a therapeutic agent, and non of the listed therapeutic agents of the specification are known as pharmaceutically acceptable carriers for cells.

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carlos A. Azpuru whose telephone number is (571) 272-0588. The examiner can normally be reached on Tu-Fri, 6:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone

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number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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